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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,368

11/19/2003

James H. Layer

GCC-108

9505

35996

7590

06/27/2005

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,368

[illegible]

LAYER, JAMES H.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/6/2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11 is/are rejected.
- 7) ☒ Claim(s) 4 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/30/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 10 is objected to because of the following informalities: The term "member" should be changed to "chamber". In claim 9, the chamber was recited as having an hourglass shape. This claim was examined with the assumption that the "chamber" and the "member" were referencing the same structure. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (5,895,376).

Schwartz et al. clearly discloses two embodiments of a hemostasis valve that include all of the limitations as recited in claim 1. See Figures 1 and 2 and the respective portions of the specification. The first embodiment is illustrated in Figure 1 and the second embodiment is illustrated in Figure 2. Schwartz et al. discloses a hemostasis valve that has a valve body (12) that has a proximal end (14) and distal end (16) that connect to other medical devices. The valve body has a first elongated chamber defined by the portion of element (20) that extends from element (44) to element (22) in Figure 1. The first elongated chamber has a lumen that receives

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medical instrument (19). A collapsible member (22) defines the first elongated chamber. The valve body has a second elongated chamber (30) that surrounds the first elongated body and has a greater volume than the first elongated chamber. The hemostasis valve has a pressure application system that consists of elements (40) and (41). The movable member (41) rotates within the second chamber (30) and increases the pressure on collapsible member (22), which in turn seals around the medical instrument (19).

The second embodiment as seen in Figure 2 also includes all of the limitations as recited in claim 1. The valve body (12) has a proximal (14) and a distal (16) end for connecting to other medical devices. A first elongated chamber is defined as the portion of element (20) that lies between the proximal and distal ends of element (61) as seen in Figure 2. A collapsible member (22) surrounds the first elongate chamber. A second elongated chamber (30) surrounds the first elongated chamber and has a greater volume than the first elongated chamber. The hemostasis valve of the second embodiment also has a pressure application system made up of elements (60) and (62). The moveable member (61) squeezes the second chamber (30) to increase the pressure within the chamber and as a result the collapsible member (22) seals around the medical instrument (19).

In regards to claim 2, Schwartz et al. discloses an embodiment of a hemostasis valve that includes all of the limitations as recited in claim 1 wherein the moveable member (61) of the second embodiment is a plunger that moves relative to the valve body (12) to reduce the volume of the second chamber (30). Element (61) meets the

broadest possible interpretation of a plunger which is "a sliding reciprocating piece driven by or against fluid pressure". Element (61) slides past element (57) and moves against the fluid pressure from the second chamber (30).

In regards to claim 3, Schwartz et al. discloses an embodiment of a hemostasis valve that includes all of the limitations as recited in claim 2 wherein the longitudinal axis of the plunger (61) in Figure 2 extends parallel with the axis of the valve body (12).

In regards to claim 8, Schwartz et al. discloses an embodiment of a hemostasis valve that includes all of the limitations as recited in claim 1 wherein an infinite amount of pressure adjustments can be made to the second elongated chamber (30) of the first embodiment. The pressure is adjusted by twisting the handle (40) and there are an infinite number of twists that can be applied to the handle.

In regards to claim 9, Schwartz et al. discloses an embodiment of a hemostasis valve that includes all of the limitations as recited in claim 1 wherein the second elongated chamber (30) in the second embodiment as seen in Figure 2 has a substantially hour glass shape.

In regards to claim 10, Schwartz et al. discloses an embodiment of a hemostasis valve that includes all of the limitations as recited in claim 9 wherein the valve body (12) of the second embodiment has a housing (54) that forms a seal with the first and second bulbous sections of the elongated chamber (30). See Figure 2.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Catlin (5,195,980).

Catlin discloses a hemostasis valve that includes all of the limitations as recited in claim 1. See Figures 1-4 and the respective portions of the specification. Catlin discloses a hemostasis valve that comprises a valve body (36) that has proximal and distal ends for connecting to other medical devices. The valve body (36) has a first chamber defined by the area enclosed by a collapsible member (42) and element (40). The second elongated chamber is defined as the area within the valve body (36), which extends around the first chamber and has a greater volume than the first chamber. The hemostasis valve also includes a pressure application system that comprises a moveable member (50) that moves within the second chamber. The moveable member (50) increases the pressure inside the second chamber and causes the collapsible member (42) to seal around the received medical instrument.

In regards to claim 2, Catlin discloses a hemostasis valve that includes all of the limitations as recited in claim 1 wherein the moveable member (50) is a plunger.

In regards to claim 3, Catlin discloses a hemostasis valve that includes all of the limitations as recited in claim 2 wherein the longitudinal axis of plunger (50) is substantially parallel to the longitudinal axis of the valve body (36).

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Mollenauer et al. (5,514,109).

Mollenauer et al. discloses a hemostasis valve that includes all of the limitations as recited in claim 1. See Figures 7 and 8 and the respective portions of the specification. Mollenauer discloses a hemostasis valve with a valve body (100) that has proximal and distal ends to connect to medical devices. The valve body has a first

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elongated chamber defined by the area enclosed by the collapsible member (106) and the extension sleeve (140). The valve has a second elongated chamber defined as the area between the valve body (100) and the first elongated chamber. The valve also has a pressure application system comprising a moveable member defined as elements (111, 115, and 110) that moves within the second elongated chamber and increases the pressure in the first elongated chamber and causes the collapsible member (106) to seal around the medical device (C). See Figure 8.

Mollenauer et al. discloses a method of sealing a hemostasis valve about a medical instrument that includes all of the limitations as recited in claim 11. The inherent use of the valve disclosed by Mollenauer et al. meets the steps disclosed in claim 11. A medical instrument (C) is positioned within the first chamber (defined above) of the valve body (100) of the hemostasis valve. A pressure-increasing element (111, 115, and 110) is advanced within the second chamber of the valve body and the collapsible member (106) seals around the catheter. This method is illustrated in Figures 7 and 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catlin (5,195,980) in view of Appling et al. (5,267,979).

Catlin discloses a hemostasis valve that includes all of the limitations as recited in claim 1 wherein the moveable member (50) has a housing defined as the inner surface of element (36). Catlin does not teach to include a sealing member to the moveable member (50) to provide a seal between the moveable member (50) and the housing (inner surface of element 36).

Appling et al. discloses a catheter with a valve assembly attached to the proximal end. See Figure 8 and the respective portions of the specification. The valve assembly has a moveable member with an O-ring secured around it, which cooperates with the inner surface of the valve housing (108). Appling et al. teaches that the O-ring is used to provide a seal to prevent proximal fluid flow.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an O-ring, as disclosed by Appling et al., to the moveable member (50) as disclosed by Catlin to prevent fluid flow out of the hemostasis valve.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Catlin in view of Appling et al. as discussed above.

Catlin further discloses a moveable member (50) with an internal lumen that receives elongated member (52), which is able to carry a catheter (30). The internal lumen of element (52) provides a fluid tight seal when the distal portion (30a) of the catheter is passed through the lumen.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Catlin in view of Appling et al as discussed above.

Catlin further discloses an elongated member (52) that has an internal lumen that is aligned with the first chamber (defined above).

Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4723550 A to Bales
US 4726374 A to Bales
US 4886507 A to Patton
US 5242432 A to DeFrank
US 5338313 A to Mollenauer
US 5338314 A to Ryan
US 5395352 A to Penny
US 5429609 A to Yoon
US 5460616 A to Weinstein
US 5474536 A to Bonaldo

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US 5591137 A to Stevens
US 5599327 A to Sugahara
US 5782817 A to Franzel
US 5935112 A to Stevens
US 6221057 B1 to Schwartz
US 6402723 B1 to Lampropoulos
US 6575960 B2 to Becker
US 6887220 B2 to Hogendijk

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS

A handwritten signature in black ink, appearing to read 'N. Lucchesi', with a stylized, flowing script.

**NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**